

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

December 1, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW

DP Barcode: D307738, D307734

Reg. No. Or File Symbol: 6836-EIG, 6836-EIU

TO: Velma Noble\Tracy Lantz
PM Team No. 31

FROM: Chris Jiang, Chemist
Product Science Branch
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CTT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

THRU: Michele Wingfield, Branch Chief
Product Science Branch
Antimicrobials Division (7510C)

CJ

A handwritten signature in cursive script, appearing to read "Karen P. Hicks".

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BACKGROUND:

The registrant has submitted a product chemistry package in response to the review done under D284728. The package includes studies that have been identified by the Agency as MRID's 46332202, 46309706, and 46309707.

FINDINGS:

1. The registrant appears to want the data for Lonzac 12 to cover the requirements for Lonza Formula LN2-64. This cannot be done because the end-use product contains an additional active ingredient of didecyl dimethyl ammonium chloride. The registrant will have to submit new data.
2. In the review done under D284728, the Agency has asked that the analytical method for one of the impurities be submitted; however, this was not addressed in this submission. MRID 46332202 states that the enforcement analytical method was submitted under 45115301; however, the enforcement analytical method is not addressed. In the review done under D284737, the data submitted for the enforcement analytical method was **unacceptable**. Three batches of the end-use product appear to have been analyzed only for didecyl dimethyl ammonium chloride. No analysis appears to have been done for bis (3-aminopropyl) dodecylamine that was formulated in Germany. A five-batch analysis is needed for registration.
3. MRID 46309706 is **unacceptable**. The study was only conducted for only seven days using carbon steel coupons. Agency guidelines require that the test for corrosion characteristics be conducted for one year. While no corrosion was observed in the study, carbon steel is known to corrode so the coupons may have been just beginning to corrode. The test for corrosion characteristics must be conducted for one year.
4. MRID 46309707 is **acceptable**. At 25 °C, the respective mean active concentrations of two replicates of bis (3-aminopropyl) dodecylamine at pre-storage, at 98 days, at 187 days, and at 366 days were 91.7 %, 91.2 %, 90.8 %, and 91.5 %. At all time intervals, the test substance was a colorless homogeneous liquid. At pre-storage, there was an insoluble white precipitate. According to the study, there is no record of the white precipitate being transferred to the storage containers.

51-98071-A

RECOMMENDATIONS:

1. Product Science Branch of Antimicrobials Division finds this submission to be unacceptable for the reasons stated in the findings. The registrant needs to remedy the deficiencies mentioned in the findings for registration to proceed.

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